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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/538,242	03/23/2007	Ralf Dunkel	CS8535/LeA 36,334	3635
34469 BAYER CRO	7590 09/02/200 PSCIENCE LP	EXAMINER		
Patent Department 2 T. W. ALEXANDER DRIVE RESEARCH TRIANGLE PARK, NC 27709			SAEED, KAMAL A	
			ART UNIT	PAPER NUMBER
TO SEE THE E	iniii (OSE i i inii, i (O	27703	1626	
			NOTIFICATION DATE	DELIVERY MODE
			09/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Application No. Applicant(s) 10/538,242 DUNKEL ET AL.

Office Action Summary	Examiner	Art Unit				
·	Kamal A. Saeed	1626				
The MAILING DATE of this communication app			ddress			
Period for Reply	ears on the cover sheet with the c	orrespondence ac	idress			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DY Extensions of time may be available under the provisions of 37 CPR 1.3 after SIX (6) MONTHS from the mailing date of this communication. Failur to roply within the six or extended period for riply will. by statute, Any reply received by the Office later than three months after the mailing carried patent term adjustment. See 37 CPR 1.70(4).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this o D (35 U.S.C. § 133).				
Status						
Responsive to communication(s) filed on						
2a) This action is FINAL. 2b) This	- '					
3) Since this application is in condition for allowar	nce except for formal matters, pro	secution as to the	e merits is			
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	3 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>15-27</u> is/are pending in the application						
4) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.	Without consideration.					
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) 15-27 are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examine	-					
		Evaminer				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correct			FR 1.121(d).			
11) The oath or declaration is objected to by the Ex						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	-(d) or (f).				
a) All b) Some * c) None of:	- h h					
Certified copies of the priority documents have been received.						
Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau	•	a in this reactorial	Stage			
* See the attached detailed Office action for a list		ıd.				
Attachment(s)						
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Interview Summary Paper No(s)/Mail Da					
3) Information Disclosure Statement(s) (PTO/S5/08)	5) Notice of Informal P					

Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3). Information Disclosure Statement(s) (PTO/SE/08) Pager Mork (Midd) Index	4) Interview Summary (PTO-413) Paper No(s)/Mail Date. 5) Notice of Informal Patent Application	
Paper No(s)/Mail Date	6)	

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DETAILED ACTION

Claims 1-14 have been canceled. Therefore, claims 15-27 are pending in the instant application and are subject to the following lack of unity requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 15-18 and 20 drawn to products of formula (I). If this group is elected, a further election of a single disclosed species is also required.

Group II, Claims 19 and 22, drawn to a process of preparing products of formula

(I). If this group is elected, a further election of a single disclosed species is also required.

Group III, Claim 23, drawn to products of formula (III). If this group is elected, a further election of a single disclosed species is also required.

Group IV, Claim 24, drawn to products of formula (V). If this group is elected, a further election of a single disclosed species is also required.

Group V, Claim 25, drawn to products of formula (VI). If this group is elected, a further election of a single disclosed species is also required.

Group VI, Claim 26, drawn to products of formula (VIII). If this group is elected, a further election of a single disclosed species is also required.

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Group VII, Claim 27, drawn to products of formula (XIV). If this group is elected, a further election of a single disclosed species is also required.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under 35 USC 121 or PCT Rule 13.1 because they lack the same or corresponding special technical features:

In the instant case, at least one Markush alternative is not novel because prior art recites a species of the generic invention (see U.S. Patent No. 5,556,988, column 13, compound IV), (cited in the IDS), thus the lack of a special technical feature is apparent. As such, there is no special technical feature defining a contribution which each of the inventions, considered as a whole, makes over the prior art. Therefore, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-VII and between Markush species is broken.

Election of Species

 This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Regardless of Group elected, an election of a single compound is further required, including an exact definition of each substitution on the base molecule (Formula (I)), wherein a single member at each substituent group or moiety is selected.

For example, if a base molecule has a substituent group R3, wherein R3 is recited to be

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any one of $NR_{13}(C=X_2)R_{12}$, $NR_{13}(C=X_1)R_{12}$, $NR_{13}SO_2R_{14}$, etc., then applicant must select a single substituent for R3, for example $NR_{13}SO_2R_{14}$, and each subsequent variable position. A drawing of the exact chemical structure is required. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Where an election of Group I is made, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not

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be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 applies with regard to double patenting covering divisional applications.)

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds, which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

The species included in the above inventions do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

a)Each chemical species is a distinct chemical lacking a special technical feature in view of that at least a species of the generic invention has been disclosed in the prior

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art (see Alberti et al. II Farmaco. 1962, Ed. Sc. Vol. 17, No. 6, p. 460-467, compound III of page 461), (cited in the international search report and provided by applicants).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C.§ 103(b)," 1184 O.G. 86 (March 26, 1996).

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Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include all the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed whose telephone number is (571) 272-0705. The examiner can normally be reached on M-T 7:00 AM- 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not

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communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/Kamal A Saeed/

Primary Examiner, Art Unit 1626